

Amendments to the Drawings:

The attached sheets of drawings include changes to FIGs. 6, 7, 9, 10, and 11. FIG. 6 has been amended to clarify the interconnection between the working solution inlet tube 210 and the working solution distribution tubing 212 and also to clarify that numeral 214 refers to the break-away closure (i.e. the small rectangular box) on the inlet tube 204. FIG. 7 has been amended to change reference numeral 102 to 104. FIG. 9 has been amended to change reference numeral 810 to 801. FIG. 10 has been amended to remove reference numeral 806. FIG. 11 has been amended to change reference numeral 810 to 801 and to add reference numeral 803.

Attachment: 23 Replacement Sheets

REMARKS/ARGUMENTS

1. Claims 1-27 are pending. Claims 15-20 are withdrawn as being directed to a non-elected invention. Applicants respectfully request reconsideration of the application in view of the above-amendments and the following remarks and arguments.

2. The Examiner rejected claims 1-5, 8-11, 21-24, 26 and 27 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 4,798,580 (DeMeo et al., hereinafter DeMeo); rejected claim 6 under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over DeMeo; and rejected claim 7 under 35 U.S.C. §103(a) as being unpatentable over DeMeo in view U.S. Patent 5267956 (Beuchat).

Within the context of the subject patent application, a control assembly is used to pneumatically operate a pump cassette, specifically by applying pneumatic pressure to various pump chambers and valves of the pump cassette. As discussed in the background section of the subject patent application, it is important to ensure appropriate sealing alignment and close face-to-face contact between the cassette and control assembly. Thus, as discussed in the detailed description section of the subject patent application, embodiments of the claimed invention use a movable member (e.g., a piston operated by an inflatable bladder) to sealingly press the pump cassette against the control assembly. Claims 1 and 21 have been amended to clarify the context for the claimed invention, although Applicants respectfully submit that such context was implicit in the original claims and therefore that such amendment is not made for reasons relating to patentability and should not be treated as such.

In contrast, both DeMeo and Beuchat relate to peristaltic pumps that are mechanically operated, specifically by pressing a tube contained within a pump cassette against a rotating pump head. Neither DeMeo nor Beuchat includes a control assembly that pneumatically operates the pump cassette and a movable member to sealingly press the pump cassette against the control assembly, as required by the claims. Thus,

Applicants respectfully submit that DeMeo and Beuchat are non-analogous art that do not teach or otherwise suggest the claimed invention.

3. The Examiner rejected claims 1, 24-7 (sic), 9, 10, 12-14, 21 and 25 et al. under §112(1) as lacking enablement. Applicants respectfully submit that there is ample support and enablement for the claims. For example:

A. Independent claim 1 requires, in relevant part, a control assembly for operating the pump cassette and a force assembly having a movable member capable of applying force to the pump cassette to press the pump cassette against the control assembly. The following passages from the detailed description may be relevant:

Page 3, line 16: **the control assembly** typically includes a front surface that is sealingly **pressed against** a rear surface of **the pump cassette**. The front surface of the control assembly includes membranes that align with chambers and valves in the cassette. The membranes in **the control assembly** are pneumatically controlled to inflate and deflate in a manner that **precisely controls operation of** corresponding valves and chambers **in the cassette**.

Page 7, line 17: **the force assembly includes a movable member capable of applying a continuous force to the pump cassette to press the pump cassette against the control assembly**.

Page 8, line 18: Referring back to FIG. 1, the process continues to step 2004 by **providing a control assembly capable of operating the pump cassette** 202. The control assembly includes pneumatic pathways that interface with a receiving surface through which the pump cassette 202 is operated. The receiving surface may be, without limitation, a bezel gasket that is part of a bezel assembly. **During operation, the pump cassette 202 is aligned and pressed against the bezel gasket by a movable member**, as discussed below. Air lines connected to the bezel assembly are controlled pneumatically,

and used to displace membranes of the bezel gasket to operate the various valves and chambers of the pump cassette 202.

Page 11, line 3: After inserting the pump cassette into the cassette receptacle, **a movable member is moved against at least one of the cassette receptacle and the pump cassette 202 to press the pump cassette 202 against the control assembly 408,** in block 2008. Advantageously **pressing the pump cassette 202 against the control assembly** 408, as opposed to pressing the control assembly 408 against the pump cassette 202, results in fewer tolerance accumulations, since the control assembly is typically coupled to a larger number of components that would apply various forces on the control assembly. The force applied by the movable member on the pump cassette 202 ensures a proper seal between the pump cassette 202 and the control assembly 408.

B. Claim 2 requires the movable member of the force assembly to include an expandable member capable of expanding to press the pump cassette against the control assembly, while Claim 3 points out that the expandable member could be a bladder. The following passages from the detailed description may be relevant:

Page 4, line 14: the means for applying force to the pump cassette includes an **expandable member, such as a bladder, that is capable of expanding to press the pump cassette against the operating means.**

Page 11, line 14: **The movable member may be an expandable member, such as a bladder.** Among other things, the bladder may be made from an elastic, resilient, and/or flexible material(s). A pneumatic circuit may be precisely controlled to inflate the expandable member with a predetermined amount of air. The predetermined amount of air may be programmable based on characteristics of the particular pump cassette 202. In other exemplary embodiments, the moving member may be a rigid structure whose movement is controlled by, for example, a motor.

The movable member may be attached to a door assembly that allows access to the cassette receptacle, such that the cassette pump 202 can be loaded and/or aligned. The

door assembly may also help to prevent accidental opening of the door during blood processing, as described in more detail below.

C. With respect to claims 4-7, the following passages from the detailed description may be relevant:

Page 3, line 4: The force member may include a door, the movable member coupled to the door. The force member may include a back plate and a frame, with the movable member positioned between the back plate and the frame. The system may include a pneumatic circuit for controlling the movable member. The movable member may be coupled to a piston assembly which is capable of contacting the pump cassette.

Page 11, line 21: The movable member may be attached to a door assembly that allows access to the cassette receptacle, such that the cassette pump 202 can be loaded and/or aligned. The door assembly may also help to prevent accidental opening of the door during blood processing, as described in more detail below.

Page 11, line 26: FIG. 4A shows an exploded view of a door assembly 402 in accordance with an embodiment of the present invention. Among other things, the door assembly 402 may include a door cowl 701, a latch spring post 702, a door latch 703, a cassette receptacle 704, a back plate 705, a latch pin 706, a bladder 707 with an attached pneumatic circuit 730, a piston assembly 711 ...

Page 12, line 7: As shown in FIG. 4A, the bladder 707 may be coupled to a piston assembly 711 that provides a surface for making contact with the pump cassette 202 and/or cassette receptacle 704

D. With respect to claim 9, requiring an inclusion of a cassette receptacle, wherein the force assembly is movably coupled to the control assembly to allow access to the cassette receptacle, the following passages from the detailed description may be relevant:

Page 12, line 7: As shown in FIG. 4A, the bladder 707 may be coupled to a piston assembly 711 that provides a surface for making contact with the pump cassette 202 and/or cassette receptacle 704

E. With respect to claim 10, requiring a movable coupling between the cassette receptacle and the force assembly, the following passages from the detailed description may be relevant:

Page 3, line 15: For example, the force assembly may be pivotally coupled to the control assembly, or may move in a linear fashion away from the control assembly. The cassette receptacle may be movably coupled to the force assembly and/or control assembly to allow further accessibility.

Page 11, line 3: After inserting the pump cassette into the cassette receptacle, a movable member is moved against at least one of the cassette receptacle and the pump cassette 202 to press the pump cassette 202 against the control assembly 408, in block 2008.

Page 11, line 26: FIG. 4A shows an exploded view of a door assembly 402 in accordance with an embodiment of the present invention. Among other things, the door assembly 402 may include a door cowl 701, a latch spring post 702, a door latch 703, a cassette receptacle 704, a back plate 705, a latch pin 706, a bladder 707 with an attached pneumatic circuit 730, a piston assembly 711 ...

F. With regard to claims 12, 13, 14, 21 and 25, the following passages from the detailed description may be relevant:

Page 3, line 20: In still further related embodiments of the invention, the control assembly includes a bezel and a bezel gasket. The bezel gasket includes a membrane capable of being displaced to operate the pump cassette. The control assembly may include a rigid and/or fixed plate to which the bezel is attached.

Page 8, line 18: Referring back to FIG. 1, the process continues to step 2004 by providing a control assembly capable of operating the pump cassette 202. **The control assembly includes pneumatic pathways** that interface with a receiving surface through which the pump cassette 202 is operated. **The receiving surface may be, without limitation, a bezel gasket that is part of a bezel assembly.** During operation, the pump cassette 202 is aligned and pressed against the bezel gasket by a movable member, as discussed below. **Air lines connected to the bezel assembly are controlled pneumatically, and used to displace membranes of the bezel gasket** to operate the various valves and chambers of the pump cassette 202.

G. Page 12, line 7: As shown in FIG. 4A, the bladder 707 may be coupled to a piston assembly 711 that provides a surface for making contact with the pump cassette 202 and/or cassette receptacle 704. ... **The piston assembly 711 includes a rigid plate 731** made of for example, a hard plastic.

Therefore, Applicants respectfully submit that there is ample support in the specification for claims 1, 24-7 (sic), 9, 10, 12-14, 21 and 25.

4. The Examiner objected to the drawings as including certain reference characters not mentioned in the description.

The drawings and the specification have been amended to correct instances in which either a reference character was included in a figure but not mentioned in the description or a reference character was mentioned in the description but was not included in a figure. The drawings and the specification were also amended to correct certain reference characters and other minor errors and omissions. The amendment of the drawings is discussed in the section entitled **Amendments to the Drawings** above. Applicants respectfully submit that all amendments to the drawings and the specification are fully supported in the original application and no new matter has been added thereby.

5. Withdrawn claims 15 and 16 have been provisionally amended to correct a typographical error.

6. Applicants note that the Notice of References Cited refers to U.S. Patent No. 4,789,580 (Hirsch), which appears to be erroneous due to a transposition of the numbers 8 and 9 (U.S. Patent No. 4,798,580 is the DeMeo reference relied upon by the Examiner). Hirsch appears to be completely unrelated to the subject matter of this patent application.

7. All pending claims are believed to be in a form suitable for allowance. Therefore, the application is believed to be in a condition for allowance. The Applicant respectfully requests early allowance of the application. The Applicant requests that the Examiner contact the undersigned, Jeffrey T. Klayman, if it will assist further examination of this application.

8. Applicants petition for a two month extension of time. In the event that a further extension is needed, this conditional petition of extension is hereby submitted. Applicants request that deposit account number 19-4972 be charged for any fees that may be required for the timely consideration of this application.

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Respectfully submitted,

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